



BILLING CODE 3510-16-P

## **DEPARTMENT OF COMMERCE**

### **United States Patent and Trademark Office**

#### **Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures**

**AGENCY:** United States Patent and Trademark Office, Department of Commerce.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651-0024 (Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures). The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

**DATES:** To ensure consideration, comments regarding this information collection must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email:* InformationCollection@uspto.gov. Include “0651-0024 comment” in the subject line of the message.
- *Federal Rulemaking Portal:* <http://www.regulations.gov>.
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Parikha Mehta, Legal Advisor, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 571-272-3248; or by email at [parikha.mehta@uspto.gov](mailto:parikha.mehta@uspto.gov) with “0651-0024 comment” in the subject line. Additional information about this information collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

## **SUPPLEMENTARY INFORMATION:**

### **I. Abstract**

Patent applications that contain nucleotide and/or amino acid sequence disclosures meeting the definitions of 37 CFR 1.821(a) must include, as a separate part of the disclosure, a copy of the sequence listing in accordance with the requirements in 37 CFR 1.821-1.825. Applicants may submit sequence listings for both U.S. and international biotechnology patent applications. Submissions of sequence listings in international applications are governed by Patent Cooperation Treaty (PCT) Rules 5.2 and 13~~ter~~, as well as the PCT Administrative Instructions, Annex C.

The USPTO uses applicants' sequence listings during the examination process to determine the patentability of the claimed invention. The USPTO also uses sequence listings for publication of patent applications and issued patents. Sequence listings are publicly searchable after publication and/or issuance.

This information collection covers the submission of sequence listing information itself. Information pertaining to the initial filing of U.S. patent applications is collected under OMB Control Number 0651-0032, and information pertaining to the initial filing of international applications is collected under OMB Control Number 0651-0021.

Sequence listings may be submitted via the Patent Electronic System as an ASCII text file or as a Portable Document Format (PDF) file. For U.S. applications, 37 CFR 1.821(c) permits all modes of submission: paper, read-only optical disc, or electronic filing via the Patent Electronic System. Sequence listings for international applications may only be submitted on paper or through the Patent Electronic System. Sequence listings that are too large to be filed electronically through the Patent Electronic System may be submitted on read-only optical disc.

This information collection also accounts for the requirement under 37 CFR 1.821(e) that a copy of the sequence listing required by 37 CFR 1.821(c) be submitted in computer readable form (CRF) in accordance with 37 CFR 1.824. Under 37 CFR 1.821(e)–(f), applicants who submit their sequence listings on paper, read-only optical disc, or as a PDF via the Patent Electronic System must submit a copy of the sequence listing in CRF with a statement indicating that the CRF copy of the sequence listing is identical to the paper, read-only optical disc,

or PDF copy provided under 37 CFR 1.821(c). Applicants may submit the CRF copy of the sequence listing to the USPTO on read-only optical disc or other acceptable media as provided in 37 CFR 1.824. If a new application is filed via the Patent Electronic System with an ASCII text file sequence listing that complies with the requirements of 37 CFR 1.824(a)(2)–(6) and (b), and applicant has not filed a sequence listing on paper, read-only optical disc, or as a PDF file, the text file will serve as both the copy required by 37 CFR 1.821(c) and the CRF required by 37 CFR 1.821(e). Moreover, the associated statement regarding both copies being identical would not be required.

One item, Request for Transfer of a Computer Readable Form under 37 CFR 1.821(e), has been removed from this information collection. This item is no longer part of this information collection's process per a recent rulemaking (Electronic Submission of a Sequence Listing, a Large Table, or a Computer Program Listing Appendix in Patent Applications; 86 FR 57035, 10/14/2021).

## **II. Method of Collection**

The items in this information collection may be submitted to the USPTO by mail, hand delivery, or electronic submission via the Patent Electronic System.

## **III. Data**

*OMB Control Number:* 0651-0024.

*Forms:* None.

*Type of Review:* Extension and revision of a currently approved information collection.

*Affected Public:* Private sector; individuals or households.

*Respondent's Obligation:* Required to obtain or retain benefits.

*Estimated Number of Annual Respondents:* 9,550 respondents.

*Estimated Number of Annual Responses:* 28,550 responses.

*Estimated Time per Response:* The USPTO estimates that the responses in this information collection will take the public approximately 6 hours to complete. This includes the time to gather the necessary information, create the item, and submit the completed item to the USPTO.

*Estimated Total Annual Respondent Burden Hours:* 171,300 hours.

*Estimated Total Annual Respondent Hourly Cost Burden:* \$74,515,500.

Table 1: Total Burden Hours and Hourly Costs to Private Sector Respondents

Item No.	Item	Estimated Annual Respondents (a)	Responses per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time per Response (hours) (d)	Estimated Burden (hour/year) (c) x (d) = (e)	Rate <sup>1</sup> (\$/hour) (f)	Estimated Annual Respondent Cost Burden (e) x (f) = (g)
1	Sequence Listing in Application	9,500	3	28,500	6	171,000	\$435	\$74,385,000

Table 2: Total Burden Hours and Hourly Costs to Individuals or Households Respondents

Item No.	Item	Estimated Annual Respondents (a)	Responses per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time per Response (hours) (d)	Estimated Burden (hour/year) (c) x (d) = (e)	Rate <sup>2</sup> (\$/hour) (f)	Estimated Annual Respondent Cost Burden (e) x (f) = (g)
1	Sequence Listing in Application	50	1	50	6	300	\$435	\$130,500

<sup>1</sup> 2021 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); pg.F-27. The USPTO uses the average billing rate for intellectual property attorneys in private firms which is \$435 per hour. (<https://www.aipla.org/home/news-publications/economic-survey>).

<sup>2</sup> Ibid.

*Estimated Total Annual Respondent Non-hourly Cost Burden: \$1,483,936.*

There are no maintenance costs, capital start-up costs, or recordkeeping costs associated with this information collection. However, the USPTO estimates that the total annual (non-hour) cost burden for this information collection, in the form of filing fees and postage, is \$1,483,936.

### Filing Fees

In accordance with 35 U.S.C. 41(a)(1)(G), the USPTO charges a fee for submitting a sequence listing as part of a U.S. patent application or as part of an international patent application entering the U.S. national stage if the sequence listing (i) is not filed via the Patent Electronic System or on an electronic medium in compliance with 37 CFR 1.52(e) and 1.821(c) or (e), and (ii) causes the application to exceed 100 pages. See 37 CFR 1.52(f).

Under 37 CFR 1.16(s) for U.S. patent applications and 1.492(j) for international patent applications entering the national stage, if the patent application inclusive of sequence listings filed on paper or on a non-compliant electronic medium exceeds 100 pages, the application size fee is \$420 (or \$210 for small entities and \$105 for micro entities) for each additional 50 pages or fraction thereof. The average length of a sequence listing filed on paper or in PDF format is 150 pages, which results in an average total size fee of \$1,260 (\$630 for small entities, \$315 for micro entities) for applications that are 100 pages long prior to adding the sequence listing.

As a Receiving Office under the Patent Cooperation Treaty, the USPTO collects a basic international filing fee for each international application it receives.

The basic international filing fee only covers the first 30 pages of the international application. For each additional application page in excess of 30, a size fee of \$16 is added to the basic international filing fee. The average length of a sequence listing in an international application filed on paper or in PDF format is 150 pages. As a result, a paper- or PDF-filed international application including a sequence listing incurs an estimated \$2,400 size fee when the application already includes 30 pages prior to adding the sequence listing.

The USPTO charges a fee for the handling of mega sequence listings. There are two tiers of fees related to different sequence listing sizes: one tier for file sizes between 300 MB and 800 MB and one tier for file sizes greater than 800 MB.

The USPTO also charges a Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter to encourage timely filing of sequence listings in international applications and to facilitate the effective administration of the patent system.

Table 3: Filing Fees

Item No.	Item	Estimated Annual Responses	Filing Fee (\$)	Non-hourly Cost Burden
		(a)	(b)	(a) x (b) = (c)
1	Size fees under 37 CFR 1.16(s) and 1.492(j), undiscounted entity	130	\$1,260	\$163,800
1	Size fees under 37 CFR 1.16(s) and 1.492(j), small entity	65	\$630	\$40,950
1	Size fees under 37 CFR 1.16(s) and 1.492(j), micro entity	25	\$315	\$7,875
1	Size fees for international applications	420	\$2,400	\$1,008,000
1	Submission of sequence listings of 300 MB to 800 MB (undiscounted entity)	30	\$1,060	\$31,800

1	Submission of sequence listings of 300 MB to 800 MB (small entity)	30	\$530	\$15,900
1	Submission of sequence listings of 300 MB to 800 MB (micro entity)	10	\$265	\$2,650
1	Submission of sequence listings of more than 800 MB (undiscounted entity)	2	\$10,500	\$21,000
1	Submission of sequence listings of more than 800 MB (small entity)	1	\$5,250	\$5,250
1	Submission of sequence listings of more than 800 MB (micro entity)	1	\$2,625	\$2,625
1	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13 <del>ter</del> (undiscounted entity)	215	\$320	\$68,800
1	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13 <del>ter</del> (small entity)	700	\$160	\$112,000
1	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13 <del>ter</del> (micro entity)	8	\$80	\$640
	<b>Total</b>	---	---	<b>\$1,481,290</b>

### Postage

Although the USPTO prefers that the items in this information collection be submitted electronically, responses may be submitted by mail through the United States Postal Service (USPS). The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail 2-day flat rate legal envelope, will be \$9.25. The USPTO estimates that 1% sequence listings will be submitted in the mail resulting in 286 mailing submissions . Therefore, the USPTO estimates the total mailing costs for this information collection at \$2,646.

## **IV. Request for Comments**

The USPTO is soliciting public comments to:



- (a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected; and
- (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. The USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, the USPTO cannot guarantee that it will be able to do so.

**Kimberly Hardy,**  
*Information Collections Officer,*  
*Office of the Chief Administrative Officer,*  
*United States Patent and Trademark Office.*

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